

DAC-SpectroMed S.R.L. Chisinau	Declaration of EC-Conformity	File No.	F-PS-10-05
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DAC-SpectroMed SRL

Nicolae Testemitanu str. 37

MD-2025, Chisinau

Republic of Moldova

hereby declares under its own responsibility that the *in-vitro diagnostics* medical devices for latex agglutination and hemagglutination tests **listed in Annex I**

- are in accordance with the Annex I of the EC Council Directive 98/79/EC from 27th October 1998 on in-vitro diagnostic medical devices;
- conform to the relevant provisions of the EC Council Directive 98/79/EC from 27th October 1998 on in-vitro diagnostic medical devices.

Harmonized standards applied:

EN ISO 9001:2015

EN ISO 14971:2012

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 23640:2011

EN ISO 13612:2002

EN ISO 15223-1:2012

EN ISO 13485:2016

DAC-SpectroMed SRL has a Quality System in place based on EN ISO 9001:2015 and EN ISO 13485:2016, issued by the IQNet&SRAC.

Our Authorized Representative in EU is Qarad B.V., with address at Flight Forum 40, 5657 DB Eindhoven, The Netherlands



General Manager

Virschi Roman

16.07.2019

Head of Normative-Technical Documentation
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16.07.2019

Annex I

Declaration of Conformity according to European Directive of in vitro diagnostic medical devices (98/79/EG) of the Medical Devices Act (MPG)

Cat. No	Product	Method	Cornformity
1033C100	CRP-Latex	Slide agglunation	CE
1033C200	CRP-Latex	Slide agglunation	CE
1033C250	CRP-Latex	Slide agglunation	CE
1033C500	CRP-Latex	Slide agglunation	CE
1031A100	ASLO-DAC	Slide agglunation	CE
1031A200	ASLO-DAC	Slide agglunation	CE
1031A250	ASLO-DAC	Slide agglunation	CE
1031A500	ASLO-DAC	Slide agglunation	CE
1039R100	RefaTex-DAC	Slide agglunation	CE
1039R200	RefaTex-DAC	Slide agglunation	CE
1039R250	RefaTex-DAC	Slide agglunation	CE
1039R500	RefaTex-DAC	Slide agglunation	CE
1038R200	RefaTex-conf	Slide agglunation	CE
1041R100	ReumoScreen-DAC	Slide agglunation	CE
1045W100	Waler-Rose-DAC	Slide agglunation	CE
1035I100	IM-DAC	Slide agglunation	CE
1040R100	RPR-Carbon-DAC	Slide agglunation	CE
1040R250	RPR-Carbon-DAC	Slide agglunation	CE
1040R500	RPR-Carbon-DAC	Slide agglunation	CE
1040R1000	RPR-Carbon-DAC	Slide agglunation	CE
1043S100	SLE-DAC	Slide agglunation	CE
1044T100	TPHA-DAC	Microplate agglutination	CE
1044T200	TPHA-DAC	Microplate agglutination	CE
1047C100	Candida-Latex	Slide agglunation	CE
1049T100	Trihomono-Latex	Slide agglunation	CE
1051D50	D-dimer-DAC	Slide agglunation	CE
1054A50	AntiSperm-Latex	Slide agglunation	CE
1053A50	AntiOvary-Latex	Slide agglunation	CE
1032C435	CIC-DAC	End point	CE
1036N305	NBT-DAC	End point	CE